LETTERS TO THE EDITOR

New cardiovascular risk determinants do exist and are clinically useful

I read with interest the article by Smulders et al., in which the authors noted that the key to understanding a statistically significant relationship between independent risk predictors, but no improvement in risk classifications, lies with the statistical methodology used for the assessment. But, it seems to me that the final criteria for defining biomarkers for clinical use must be from information obtained from well-designed prospective studies that show clinical management can be altered on the basis of information obtained from well-designed prospective outcome studies that show clinical management can be altered on the basis of test results leading to improved outcomes, in an economically reasonable way. The statistical tests used to evaluate studies performed prior to outcome studies (preliminary studies) help in pointing towards which biomarkers might show sufficient diagnostic discrimination to be tested in what may be large expensive prospective studies that define clinical outcome.

In their article, Smulders et al. discussed a number of statistical techniques that may be used in preliminary studies to assess biomarkers for outcome studies. These include c-statistic, risk ratio/odds ratio (RR/OR), and reclassification. It has been demonstrated that RR/OR is more sensitive for identifying biomarkers than c-statistic. For inflammatory markers tested, so far there is a problem in defining criteria for determining which truly is a risk factor whose modification directly reduces risk perform with regard to the prediction of future cardiovascular risk. In my view, the problem with new biomarkers, tested so far, is that the weak relationships make the challenge great in terms of design and cost for prospective-outcome studies that are apt to fail.

References

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New cardiovascular risk determinants do exist and are clinically useful: reply

Dr Levinson remarks that the clinical value of biomarkers can only be defined in studies showing improved outcome after